Surginetics™

K062350

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FEB 26 2007

October 12, 2006

510(k) SUMMARY

Contact Name: Maneta Lollar, Director of Regulatory Affairs and Quality Assurance

Name of Device:

Proprietary Name: Surginetics AdvantageBlade™

Classification Name: Electrosurgical Electrodes

Classification: Class II, Electrosurgical cutting and coagulation device and accessories, General and plastic surgery (21 CFR 878.4400)

Product Code: GEI

Intended Use

The Surginetics AdvantageBlade is intended as an alternative to uncoated stainless steel as well as coated electrodes for use in conventional monopolar electrosurgical accessories. The AdvantageBlade is intended for use in situations where monopolar electrosurgery is used.

Product Description

The Surginetics AdvantageBlade is a coated blade intended for use as a monopolar electrosurgical accessory. The blade reduces the smoke emitted into the surgical area, uses lower wattages with less tissue damage and the coating provides a surface that facilitates ease of cleaning of tissue residues that may accumulate during use. The coating provides for ease of eschar cleaning.

The blades are intended for use with monopolar electrosurgical accessories and will be packaged separately. The coated blades will also fit in currently marketed electrosurgical pencils offered by other manufacturers.

Statement of Substantial Equivalence

Surginetics AdvantageBlade is substantially equivalent in function and intended use to the following legally marketed devices:

1. Valleylab Uncoated E1551X
2. Valleylab Coated E1450X EDGE

For additional information see the information in Tables 1, A3-1, and A3-2.

Safety and Performance

1. Biocompatibility Testing

The biological safety of the Surginetics AdvantageBlade has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The components of the blades have incidental short term contact with patient tissues at the surgical site.

2. Performance Testing

Performance testing was performed on prototype Surginetics AdvantageBlade electrodes. The configuration is representative of the range of electrodes that will be available in coated form.

Testing that adjusted the power from an electrosurgical generator (a Valleylab Force FX) until a particular blade cut effectively was used to obtain most of the performance data. This test, which is called a Titrated Power Test because it adjusts the power until effective cutting occurs, was used to determine the power level at which effective cutting occurred, the amount of delay and drag during cutting, the amount of smoke produced, the amount of eschar accumulated, and the amount of tissue damage. The tissue sample used was fresh beef liver (about six hours old). Beef liver is used because its consistency and size enables high quality comparisons.

Another test, the Insulation Penetration Test, carefully placed a sharp penetrator on the insulated surface of a coated blade and then periodically increased the load on the penetrator and measured the time until the penetrator pushed through the insulating coating and contacted the underlying metal blade.

- Electrode low power cutting

The Surginetics AdvantageBlade starts cutting effectively at lower power than the predicate uncoated and coated blades. Refer to Table A3-1 for the test data.

- Initial delay/drag

The Surginetics AdvantageBlade produced less drag at startup than the predicate uncoated and coated blades. Refer to Table A3-1 for the test data.

- Electrode smoke plume production

The Surginetics AdvantageBlade produced less smoke than the predicate uncoated and coated blades. Refer to Table A3-1 for the test data.

- Electrode eschar accumulation

The Surginetics AdvantageBlade produced less eschar than the predicate uncoated and coated blades. Refer to Table A3-1 for the test data.

- Tissue damage

The Surginetics AdvantageBlade produced less tissue damage than the predicate uncoated and coated blades. Refer to Table A3-1 for the test data.

- Coating penetration

The Surginetics AdvantageBlade demonstrated better mechanical integrity when subjected to mechanical penetration forces than the predicate coated blades. This characteristic is not germane for uncoated blades. Refer to Table A3-2 for the test data.

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Table A3-1 Test Results for Titrated Power Test (Lower numbers are better)					
	Power when cutting started (WATTS)	Delay/Drag Score	Smoke Score	Eschar Score	Tissue Damage Score
Valleylab E1551X (uncoated)					
Blade #1	15	60	48	48	46
Blade #2	15	10	45	42	46
Blade #3	15	10	45	42	46
Mean	15	27	46	44	46
Valleylab E1450X EDGE (coated)					
Blade #1	25	200	49	52	46
Blade #2	20	50	40	30	46
Blade #3	20	70	35	25	46
Mean	21.7	107	41	36	46
Surginetics Advantage Blade					
Blade #1	10	5	0	1	0
Blade #2	5	7	0	0	0
Blade #3	5	12	0	0	0
Mean	6.667	8	0	.3	0

Some of the differences in the test results are large enough that it may appear that errors exist. That is not the case. Noticeable differences exist in the results. For example, the Delay/Drag score for Valleylab E1450X EDGE Blade #1 is 200 because that blade had more drag during both of the cuts made with it. Similarly, both Valleylab blades

produced clouds of smoke and caused tissue damage (dark brown cooked tissue appearance) and the AdvantageBlade devices did not produce any smoke and left the tissue looking as if it had been cut with a sharp steel scalpel. Similar differences were noted in the Eschar scores.

The Delay/Drag scores for the AdvantageBlade electrodes are low because the blades gave the distinct impression of gliding through the tissue. The other blades produced delays at the start of cutting or dragged, or both.

Table A3-2
Test Results for Insulation Penetration Test
(Larger numbers are better)

	Elapsed Time until Insulation Failed (Seconds)	Final Weight Driving Penetrator (Grams)	Comments
Valleylab E1450X EDGE (coated)			
Blade #1	0.1	7.33	Failed immediately
Blade #2	0.1	7.33	Failed immediately
Blade #3	0.1	7.33	Failed immediately
Mean	0.1	7.33	
Std. Dev.	0	0	
Surginetics Advantage Blade			
Blade #1	200-stopped test	83	Never failed
Blade #2	200-stopped test	83	Never failed
Blade #3	200-stopped test	83	Never failed
Mean	200-stopped test	83	
Std. Dev.	0	0	

The insulation penetration tests were carried out with meticulous care when the penetrator (an 18 gauge x 1.5 inch Monoject needle) was placed on the surface of the insulation of each blade. For example, the test fixture was configured so that it was never moved after the needle was positioned on the blade. This technique was used to prevent vibrating or otherwise causing motions that would induce the tip of the needle to work its way into the insulation and toward the metal portion of the blade. In spite of this great care, all of the Valleylab E1450X EDGE blades failed as soon as the tests started. The test results show the time being 0.1 seconds. That is the shortest time interval that the apparatus can measure. The weight of the needle and container above it that accumulates weight during the test run is 7.3 grams. Therefore, a time to failure of 0.1 seconds and a weight of 7.3 grams means that the needle's tip with no added weight penetrated the insulation within the few seconds it took to place the penetrator on the blade's surface and start the timer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB 26 2007

Re: K062350
Trade/Device Name: Surginetics AdvantageBlade™
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 9, 2007
Received: February 12, 2007

Dear Ms. Lollar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

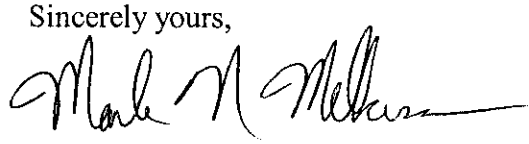
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062350

Indications for Use

510(k) Number (if known): Not assigned at this time.

Device Name: Surginetics AdvantageBlade™

Indications For Use:

The Surginetics AdvantageBlade™ coated electrodes are indicated for use in surgical procedures (general, neurosurgical, laparoscopic, orthopedic, gynecologic, etc.) where monopolar electrosurgical cutting and coagulation are normally used. The coated electrodes are an alternative to conventional monopolar electrosurgical electrodes used for these indications.

Prescription Use X **AND/OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062350